19 December 2016 Without prejudice

This **document** is the European Union's (EU) proposal for a legal text on sanitary and phytosanitary measures in the EU-Indonesia FTA. It has been tabled for discussion with Indonesia. The actual text in the final agreement will be a result of negotiations between the EU and Indonesia.

**DISCLAIMER**: The EU reserves the right to make subsequent modifications to this text and to complement its proposals at a later stage, by modifying, supplementing or withdrawing all, or any part, at any time.

## CHAPTER [XX]

## SANITARY AND PHYTOSANITARY MEASURES

## Article X.1

# **Objectives**

The objectives of this Chapter are:

- (a) to enhance the practical implementation of the principles and disciplines contained within the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter referred to as "SPS Agreement") and applicable international standards, guidelines and recommendations developed by relevant international organisations;
- (b) to protect human, animal or plant life or health in the territory of each Party while facilitating trade between the Parties and to ensure that SPS measures imposed by each Party do not create unnecessary obstacles to trade;
- (c) to provide a means to strengthen communication, cooperation and resolution on SPS issues that may affect trade between the Parties and other agreed matters of interest to the Parties;
- (d) to promote greater transparency and understanding on the application of each Party's SPS measures; and
- (e) to enhance collaboration between the Parties on animal welfare issues.

#### *Article X.2*

## Scope

- 1. This Chapter applies to all SPS measures of a Party that may, directly or indirectly, affect trade between the Parties.
- 2. This Chapter shall also apply to animal welfare matters.

3. Nothing in this Chapter shall affect the rights of the Parties under the WTO Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Chapter.

## Article X.3

### **General Provisions**

- 1. The Parties reaffirm their rights and obligations relating to SPS measures under the SPS Agreement.
- 2. Each Party commits to apply the principles of the SPS Agreement in the development, application or recognition of any sanitary or phytosanitary measure with the intent to facilitate trade among the Parties while protecting human, animal or plant life or health in the territory of each Party.
- 3. SPS measures cannot be used so as to create unjustified barriers to trade.
- 4. The Parties shall ensure that procedures established under the scope of this Chapter are undertaken and completed without undue delay and that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination against the other Party where the same conditions prevail.
- 5. In the same way, the Parties will neither use the procedures mentioned in paragraph 4 nor the requests of additional information to delay the access to the market without scientific and/or technical justification.
- 6. Each Party shall ensure that administrative procedures concerning the import requirements on food safety, animal health and plant health are not more burdensome or trade restrictive than necessary to give the importing Party adequate confidence that these requirements are met. These administrative procedures shall be set with the objective to minimise negative trade effects and to simplify and expedite the clearance process while meeting the importing Party requirements. Where official certificates are required, these shall be set in line with the principles laid down in the international standards of the Codex Alimentarius, the International Plant Protection Convention (hereinafter referred to as "IPPC") and the World Organisation for Animal Health (hereinafter referred to as "OIE") and the importing Party shall not put in place any additional administrative system that unnecessarily hampers trade or duplicates the official certificate, this includes import authorisation procedures.

## Article X.4

#### **Definitions**

For the purposes of this Chapter, the definitions contained in Annex A of the SPS Agreement shall apply.

The Parties may agree on other definitions for the application of this Chapter, taking into

consideration the glossaries and definitions of the relevant international organizations, such as the Codex Alimentarius, the OIE, and the IPPC. In the event of an inconsistency between the definitions agreed by both Parties and the definitions set out in the SPS Agreement, the definitions set out in the SPS Agreement shall prevail.

## In addition:

- (a) "import conditions" means any sanitary or phytosanitary measures as set out in Annex A of the SPS Agreement that is to be complied with for imports to reach the appropriate level of protection of the importing Party.
- (b) "protected zone" for a specific regulated pest means an officially defined geographical area in the EU in which that organism is not established in spite of favourable conditions and its presence in other parts of the territory of the Union.
- (c) "competent authorities" means those organizations recognised by each Party as responsible for developing, implementing and administering the SPS measures within its territory.

#### *Article X.5*

## **Competent Authorities and Contact Points**

As of the date of entry into force, the Parties shall provide the other with a description of the competent authorities for the implementation of this Chapter and a contact point for communication on all matters arising under this Chapter.

The Parties shall inform each other of any significant changes in the structure, organization and division of competency of their competent authorities and ensure that the information on contact points is kept up to date.

### Article X.6

## **Risk Assessment**

The Parties shall ensure that their SPS measures are based on a risk assessment in accordance with relevant provisions, including Article 5 of the SPS Agreement.

## Article X.7

## **Import Conditions, Import Procedures and Trade Facilitation**

1. Import conditions shall be applicable to the entire territory of the exporting Party.

The importing Party shall give consideration to any request of the exporting Party, for a review of the import conditions existing between the Parties on the date of entry into force of this Agreement.

The importing Party shall ensure full transparency on its import conditions, its import authorisation procedures and the frequency of import checks carried out on products from the other Party.

- 2. With respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, including that for approval and clearance process, the Parties shall ensure that:
  - (a) such procedures are simplified, expedited and completed without undue delay, in accordance with the SPS Agreement;
  - (b) such procedures are not applied in a manner which would constitute an arbitrary or unjustifiable discrimination against the other Party;
  - (c) the standard processing period of each procedure is published or the anticipated processing period is communicated to the applicant upon request; and
  - (d) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs.
- 3. In accordance with applicable standards agreed under the IPPC, the Parties undertake to maintain adequate information on their pest status (including surveillance, eradication and containment programmes and their results) in order to support the categorization of pests and to justify import phytosanitary measures.

The Parties shall establish lists of regulated pests and regulated commodities where a phytosanitary concern exists. The lists shall contain:

- (a) the pests not known to occur within any part of the Party's own territory;
- (b) the pests known to occur within any part of the Party's own territory and under official control; and
- (c) the pests known to occur within any part of the Party's own territory, under official control and for which pest-free areas are established.

The Parties shall make available their lists of regulated pests, regulated commodities and the phytosanitary import requirements for all regulated commodities. This information shall include, as appropriate the additional declarations, as prescribed by the importing Party.

4. Where a range of alternative sanitary or phytosanitary measures may be available to attain the appropriate level of protection of the importing Party, the Parties shall, upon request of the exporting Party, consider selecting the more practicable and less traderestrictive solution.

- 5. Where sanitary or phytosanitary certificates issued by the exporting Party are required between the Parties, the certificates shall be agreed between the Parties, taking into account international standards, guidelines or recommendation of Codex Alimentarius, OIE or IPPC.
- 6. The Parties shall promote the implementation of electronic certification and other technologies to facilitate trade.
- 7. Consignments of regulated commodities shall be accepted on the basis of adequate guarantees by the exporting Party, without:
  - (a) pre-clearance programmes. Control activities at the country of origin performed by the National Plant Protection Organisation (NPPO) of the country of destination should not be applied as a permanent import measure and only foreseen to facilitate new trade. On a voluntary basis, the NPPO of the country of origin may request pre-clearance within the inspection activities carried out by the importing countries as a trade facilitation tool;
  - (b) import licences or import permits; and
  - (c) phytosanitary protocols or work plans prescribed by the importing party.
- 8. The exporting Party shall ensure that products exported to the importing Party meet the appropriate level of protection of the importing Party. The responsibility for the implementation of adequate control measures and inspections lies with the exporting Party. The importing Party may require that the relevant competent authority of the exporting Party objectively demonstrate, to the satisfaction of the importing Party, that the import conditions are fulfilled.
- 9. The importing Party shall have the right to carry out import checks based on the sanitary and phytosanitary risks associated with importations. These checks shall be carried out without undue delay and with minimum trade disrupting effects. When products do not conform to the requirements of the importing Party, any action taken by the importing Party shall follow international standards and should be proportionate to the risk involved.
- 10. Any fees imposed for the procedures on imported products from the exporting Party shall be equitable in relation to any fees charged on like domestic products and shall not be higher than the actual cost of the service.

#### **Audit**

1. In order to attain and maintain confidence in the effective implementation of the provisions of this Chapter, the importing Party, within the scope of this Chapter, has the right to carry out audits, including:

- (a) through audit visits to the exporting Party, of all or part of the exporting Party's control and certification system, in accordance with the relevant international standards, guidelines and recommendations of the Codex Alimentarius, OIE and IPPC. The expenses of such audits shall be borne by the Party carrying out the audit; and
- (b) by requiring information from the exporting Party about its control and certification system and be informed of the results of the controls carried out thereunder.
- 2. The exporting Party shall give reasonable access to the importing Party for inspection, verification, testing, audit and other relevant procedures.
- 3. The Parties shall provide the results and conclusions of the audits carried out in the territory of the other Party.
- 4. If the importing Party decides to carry out an audit visit to the exporting Party, the visit shall be notified by the importing Party to the exporting Party at least 60 calendar days before the audit visit is to be carried out, except if agreed otherwise. Any modification to such visit shall be agreed by the Parties.
- 5. The draft report of the audit visit shall be shared with the auditee within 45 calendar days after completion of the audits. The auditee shall have 30 calendar days to comment on the draft report. Comments made by the auditee shall be attached to and, where appropriate, included in the final report. However, where a significant public, animal or plant health risk has been identified during the audit, the importing Party shall inform the auditee as quickly as possible and in any case within 10 working days following the end of the audit.
- 6. The costs incurred in carrying out the audits shall be borne by the importing Party.

### **Procedure for Listing of Establishments or Facilities**

- 1. Where establishments or facilities are required to be included on a list by the importing Party, the importing Party shall approve establishments or facilities which are situated on the territory of the exporting Party without prior inspection if:
  - (a) The exporting Party has requested such an approval for a given establishment or facility;
  - (b) The import of the product has been authorised, if so required by the competent authority of the importing Party;
  - (c) The establishment or facility concerned has been approved by the competent authority of the exporting Party;

- (d) The competent authority of the exporting Party has the authority to suspend or withdraw the approval of the establishment or facility; and
- (e) The exporting Party has provided any relevant information and appropriate guarantees requested by the importing Party.

Unless additional information is requested, the importing Party shall take the necessary legislative or administrative measures in accordance with its applicable legal procedures to allow imports within 40 calendar days of the receipt of the request of the exporting Party. If the importing Party rejects the request for approval, it shall inform without delay the exporting Party of the elements and justification upon which the decision was based.

2. The importing Party shall make its lists of approved establishments or facilities publicly available.

#### Article X.10

## **Adaptation to Regional Conditions**

Animals, animal products and animal by-products

- 1. The Parties recognise the principle(s) of zoning (and of compartmentalisation) which they agree to apply in their trade. The Parties also recognise the official animal health status as determined by the OIE.
- 2. The importing Party shall recognise the health status of zones and zoning decisions as determined by the exporting Party in accordance with the provisions of the OIE Terrestrial Animal Health Code and the OIE Aquatic Animal Health Code. The [Committee or body defined by the Agreement] referred to in Article [XX] may define further details for the procedure for the mutual recognition of such areas, taking into account any relevant SPS Agreement and OIE standards, guidelines or recommendations. This procedure will include situations related to outbreaks.
- 3. With references to paragraph 2 of this Article, the exporting Party shall if requested in exceptional cases by the importing Party, provide a thorough explanation and supporting data for the determinations and decisions covered by this Article.

The importing Party shall assess the received information within 15 working days of its receipt. Any audit the importing Party may request shall be carried out in accordance with Article X.8 (Audit).

In case the importing Party requires audit and unless otherwise agreed between the Parties, the audit shall be carried out within 25 working days following the receipt of the request.

In cases the importing party requires additional information and/or audits, the overall procedures including the decisions shall be finalised within two months, unless otherwise agreed between the Parties.

4. Where a Party considers that it has a special status with respect to any other disease not referred to in paragraphs 1 and 2, it may request recognition of this status.

## Plants and plant products

- 5. The importing Party shall recognize the determination of phytosanitary status of the exporting Party in accordance with the following provisions:
  - (a) The Parties recognize the concepts of pest-free areas, pest-free places of production and pest-free production sites, as well as areas of low pest prevalence as specified in relevant FAO and IPPC International Standards for Phytosanitary Measures (ISPM), and of protected zones which they agree to apply in their trade.
  - (b) When establishing or maintaining phytosanitary measures, the importing Party shall take into account pest-free areas, pest-free places of production, pest-free production sites, areas of low pest prevalence, as well as protected zones established by the exporting Party.
  - (c) The exporting Party shall identify pest-free areas, pest-free places of production, pest-free production sites, protected zones or areas of low pest prevalence to the other Party and, upon request of the importing Party, provide a full explanation and supporting data as provided for in the relevant ISPM or otherwise deemed appropriate. Unless the importing Party raises an objection and requests consultations within 90 working days, the regionalization decision so notified shall be understood as accepted.
  - (d) The importing Party shall assess additional information requested within 90 working days after receipt. Any verification the importing Party may request shall be carried out in accordance with Article X.8 (Audit) and within 3 months following receipt of the request for verification unless otherwise agreed between the Parties, taking into account the biology of the pest and the crop concerned.

#### Article X.11

# **Transparency and Exchange of Information**

- 1. The Parties shall:
  - (a) ensure transparency as regards SPS measures applicable to trade;
  - (b) enhance mutual understanding of each Party's SPS measures and their application;

- (c) exchange information on matters related to the development and application of SPS measures, including the progress on new available scientific evidence, that affect, or may affect, trade between the Parties with a view to minimizing negative trade effects;
- (d) upon request of a Party, communicate the requirements that apply for the import of specific products within 15 working days; and
- (e) upon request of a Party, communicate the state of play and progress of the procedure for the authorisation of specific products within 15 working days.
- 2. Each Party shall notify in writing to the other Party within 2 working days, of any serious or significant human, animal or plant life or health risk, including any food emergencies, affecting commodities for which trade takes place.
- 3. When the information referred to in this Article has been made available by notification to the WTO in accordance with the relevant rules or when the above information has been made available on the official, publicly accessible and fee-free websites of the Parties, the addresses of which are communicated to other Party, the information exchange shall be considered to have taken place.
- 4. All notifications under this Chapter shall be made to the contact points referred to under Article X.5 (Competent Authorities and Contact Points).

### **Technical Consultations**

- 1. Where a Party has significant concerns regarding human, animal, or plant life or health or concerns on measures proposed or implemented by the other Party, it can request technical consultations.
- 2. The other Party shall:
  - (a) respond to such a request no later than 30 calendar days;
  - (b) engage in the technical consultations to address these concerns; and
  - (c) make every effort to reach a mutually acceptable solution.
- 3. Each Party shall endeavour to provide the necessary information to avoid a disruption in trade and to reach a mutually acceptable solution.
- 4. Where the Parties have already established communication [channels/mechanisms/framework] for such purposes, they shall utilize them to the maximum extent possible in order to avoid unnecessary duplication.

5. The provisions of this Article do not preclude the [Committee or body defined by the Agreement] referred to in Article [XX] from considering the concerns referred to in paragraph 1.

## Article X.13

## **Emergency Measures**

- 1. If a Party adopts an emergency measure that is necessary for the protection of human, animal or plant life or health, the competent authority of the Party shall:
  - (a) immediately, and in any case no later than 24 hours, notify the competent authorities of the other Party and the contact point designated under Article X.5 (Competent Authorities and Contact Points) of such emergency measure;
  - (b) allow the other Party to make comments in writing;
  - (c) engage, if necessary, in technical consultations as referred to in Article X.12 (Technical Consultations); and
  - (d) take the comments referred to in subparagraph (b) and results of technical consultations referred to in subparagraph (c) into account.
- 2. The importing Party shall consider information provided in a timely manner by the exporting Party when making decisions with respect to consignments that, at the time of adoption of emergency measures, are being transported between the Parties, in order to avoid unnecessary disruptions to trade.
- 3. The importing Party shall ensure that any emergency measure taken under paragraph 1 is not maintained without scientific evidence. It shall review the measure with a view to avoid unnecessary trade disruption and to minimize its negative effect on trade or to replace it by a permanent measure.

## Article X.14

## Collaboration

- 1. The Parties recognise that antibiotic resistance is a serious threat to human and animal health. Antibiotic use in animal production can contribute to antibiotic resistance that may represent a risk to man. The Parties recognise that the nature of the threat requires a transnational and "One Health" approach.
- 2. Parties shall collaborate to reduce the use of antibiotics in animal production and to ban their use as growth promotors with the aim to combat antibiotic resistance in line with the "One Health" approach.
- 3. Parties shall collaborate in and follow existing and future guidelines, standards, recommendations and actions developed in relevant international organisations,

- initiatives and national plans aiming to promote the prudent and responsible use of antibiotics in animal husbandry and veterinary practices.
- 4. Parties shall promote the collaboration in all the multilateral fora, in particular with the international standard bodies.
- 5. Parties shall promote the collaboration on animal welfare.
- 6. The [Committee or body defined by the Agreement] referred to in Article [XX] will exchange information, expertise, experiences and good practices in the field of matters covered by paragraphs 2, 3 and 4 of this Article.

# **Equivalence**

- 1. The Parties recognise that the application of equivalence that principle set down in Article 4 of the SPS Agreement is an important tool for trade facilitation and has mutual benefits for both exporting and importing Parties. A determination of equivalence may be made in relation to partial or full equivalence of sanitary and phytosanitary measures and systems.
- 2. An importing Party shall accept an exporting Party's SPS measures as equivalent if the exporting Party objectively demonstrates to the importing Party that its measures achieve the importing Party's appropriate level of SPS protection. To facilitate a determination of equivalence, a Party shall, on request, advise the other Party of the objective of any relevant sanitary or phytosanitary measures. For this purpose, reasonable access shall be given, upon request, to the importing Party for inspection, testing and other relevant procedures.
- 3. Each Party shall, upon request, enter into consultations with the aim of achieving bilateral arrangements related to the (determination of) equivalence of specified SPS measures.
- 4. The Parties shall, within three months after receipt request from exporting Party, initiate the consultation process of equivalent determination. The determination of equivalence shall be finalised without undue delay after the demonstration of equivalence of the proposed measures by the exporting Party. The importing Party shall accelerate the assessment taking into account any knowledge and past experience it has in trading with the exporting country to make the determination as efficiently as possible.
- 5. In case of multiple requests from the exporting Party, the Parties shall agree within the [Committee or body defined by the Agreement] referred to in Article [XX] on a time schedule in which they shall initiate the process.
- 6. The consideration by a Party of a request from another Party for recognition of the equivalence of its measures with regard to a specific product shall not be in itself a reason to disrupt or suspend ongoing imports from that Party of the product in question.

When an equivalence determination is made, it shall be formally recorded and apply to the trade between the Parties in the relevant area without delay.

7. Where equivalence has been determined, the Parties may agree on alternative import conditions.

[Article X.16

**Institutional Provisions**]

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